

(b) Laboratories issued a certificate of waiver—

\* \* \* \* \*

(2) Must permit announced or unannounced inspections by HHS in accordance with subpart Q of this part.

\* \* \* \* \*

(g) A laboratory with a certificate of waiver that wishes to perform examinations or tests not listed in the waiver test category must meet the requirements set forth in subpart C or subpart D of this part, as applicable.

11. In § 493.39, the introductory paragraph is republished and paragraph (a) is revised to read as follows:

**§ 493.39 Notification requirements for laboratories issued a certificate of waiver.**

Laboratories performing one or more tests listed in § 493.15 and no others must notify HHS or its designee—

(a) Before performing and reporting results for any test or examination that is not specified under § 493.15 for which the laboratory does not have the appropriate certificate as required in subpart C or subpart D of this part, as applicable; and

\* \* \* \* \*

12. The heading of subpart C is revised to read as follows:

**Subpart C—Registration Certificate, Certificate for Provider-performed Microscopy Procedures, and Certificate of Compliance**

13. In § 493.43, the heading and paragraph (a) are revised to read as follows:

**§ 493.43 Application for registration certificate, certificate for provider-performed microscopy (PPM) procedures, and certificate of compliance.**

(a) *Filing of application.* Except as specified in paragraph (b) of this section, all laboratories performing tests of moderate complexity (including the subcategory) or high complexity, or any combination of these tests, must file a separate application for each laboratory location.

\* \* \* \* \*

14. In § 493.45, a new introductory paragraph is added, the introductory paragraph (a) is republished, paragraph (a)(3) is removed, and paragraphs (a)(1), (a)(2), (d), and (f) are revised to read as follows:

**§ 493.45 Requirements for a registration certificate.**

Laboratories performing only waived tests, PPM procedures, or any combination of these tests, are not required to obtain a registration certificate.

(a) A registration certificate is required—(1) Initially for all laboratories performing test procedures of moderate complexity (other than the subcategory of PPM procedures) or high complexity, or both; and

(2) For all laboratories that have been issued a certificate of waiver or certificate for PPM procedures that intend to perform tests of moderate or high complexity, or both, in addition to those tests listed in § 493.15(c) or specified as PPM procedures.

\* \* \* \* \*

(d) In accordance with subpart R of this part, HHS will initiate suspension or revocation of a laboratory's registration certificate and will deny the laboratory's application for a certificate of compliance for failure to comply with the requirements set forth in this subpart. HHS may also impose certain alternative sanctions. In addition, failure to meet the requirements of this subpart will result in suspension of payments under Medicare and Medicaid as specified in subpart R of this part.

\* \* \* \* \*

(f) In the event of a noncompliance determination resulting in an HHS denial of a laboratory's certificate of compliance application, HHS will provide the laboratory with a statement of grounds on which the noncompliance determination is based and offer an opportunity for appeal as provided in subpart R.

\* \* \* \* \*

15. In § 493.47, the heading, paragraph (a), the introductory text of paragraphs (b) and (c), paragraph (c)(2), and paragraphs (d) and (e) are revised to read as follows:

**§ 493.47 Requirements for a certificate for provider-performed microscopy (PPM) procedures.**

(a) A certificate for PPM procedures is required—

(1) Initially for all laboratories performing test procedures specified as PPM procedures; and

(2) For all certificate of waiver laboratories that intend to perform only test procedures specified as PPM procedures in addition to those tests listed in § 493.15(c).

(b) HHS will issue a certificate for PPM procedures if the laboratory—

\* \* \* \* \*

(c) Laboratories issued a certificate for PPM procedures are subject to—

\* \* \* \* \*

(2) The applicable requirements of this subpart and subparts H, J, K, M, and P of this part; and

\* \* \* \* \*

(d) In accordance with subpart R of this part, HHS will initiate suspension, limitation, or revocation of a laboratory's certificate for PPM procedures for failure to comply with the applicable requirements set forth in this subpart. HHS may also impose certain alternative sanctions. In addition, failure to meet the requirements of this subpart may result in suspension of all or part of payments under Medicare and Medicaid, as specified in subpart R of this part.

(e) A certificate for PPM procedures is valid for a period of no more than 2 years.

16. Section 493.49 is revised to read as follows:

**§ 493.49 Requirements for a certificate of compliance.**

A certificate of compliance may include any combination of tests categorized as high complexity or moderate complexity or listed in § 493.15(c) as waived tests. Moderate complexity tests may include those specified as PPM procedures.

(a) HHS will issue a certificate of compliance to a laboratory only if the laboratory—

(1) Meets the requirements of §§ 493.43 and 493.45;

(2) Remits the certificate fee specified in subpart F of this part; and

(3) Meets the applicable requirements of this subpart and subparts H, J, K, M, P, and Q of this part.

(b) Laboratories issued a certificate of compliance—

(1) Are subject to the notification requirements of § 493.51; and

(2) Must permit announced or unannounced inspections by HHS in accordance with subpart Q of this part—

(i) To determine compliance with the applicable requirements of this part;

(ii) To evaluate complaints;

(iii) When HHS has substantive reason to believe that tests are being performed, or the laboratory is being operated in a manner that constitutes an imminent and serious risk to human health; and

(iv) To collect information regarding the appropriateness of tests listed in § 493.15 or tests categorized as moderate complexity (including the subcategory) or high complexity.

(c) Failure to comply with the requirements of this subpart will result in—

(1) Suspension, revocation or limitation of a laboratory's certificate of compliance in accordance with subpart R of this part; and

(2) Suspension or denial of payments under Medicare and Medicaid in accordance with subpart R of this part.